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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,197	06/25/2003	Jean-Francois Ollivier	8707-2159	5782

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New York, NY 10103

EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,197

Applicant(s)

OLLIVIER ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

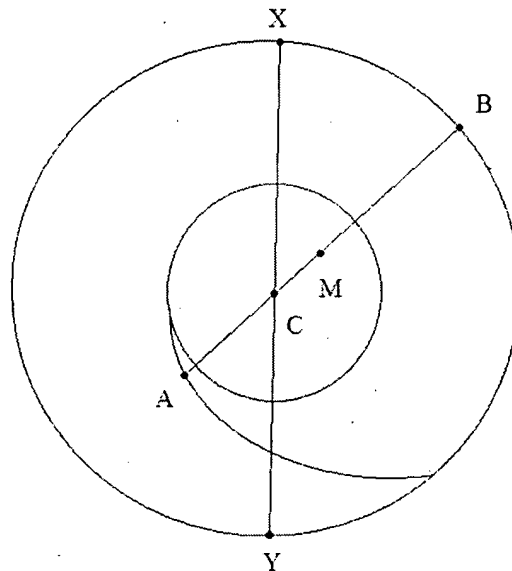
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

1. Applicant's arguments filed 9/27/06 have been fully considered but they are not persuasive. The applicant argues that Osypka does not disclose or suggest a circular contour that is eccentric relative to the axis of the cylindrical body. The Examiner respectfully disagrees. The figure shown below will help clarify the Examiner's position:



2. The inner circle of the figure represents the cylindrical body of the distal end while the outer circle represents the threads at their maximum height when viewed looking down the lead from the distal end towards the proximal end. The curved line connecting the inner and outer circles represents the thread that rises out of the cylindrical body, nearest the distal end, as shown in figures 2-4. Point C is the axis of the cylindrical body, and the threads at their maximum would also

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have an axis at point **C** since it is the midpoint of line **XY**. However, line **AB** connects the rising thread and the outer circle, and the midpoint **M** of line **AB** represents the axis of these two points. Therefore, the varying heights of the threads of Osypka do indeed create eccentric axes **M** and **C**. As a result, the 35 USC 102(b) rejection of claims 1 and 5-11 are still considered proper.

3. The 35 USC 103(a) rejections of claims 3, 4 and 12 are also still considered valid since the Applicant merely relied upon the arguments against Osypka, which have been discussed above.

Claim Rejections - 35 USC § 112

4. The amendments to claim 1 to overcome the 35 USC 112(2) rejection are acknowledged and accepted. As a result, the 35 USC 112(2) rejection of claim 1 have been withdrawn.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Osypka (US 4,550,737). Osypka discloses a coronary lead (probe) capable of being implanted in a vein of the coronary network for the stimulation of the heart (Col. 2, lines 20-25). As shown in figures 1 and 3, the lead has a hollow sheath 1b having an internal conductor 1A with a distal end 3.

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Osypka further shows an intermediate element 4a with a cylindrical body bearing a retention structure 4 and a distal end 3. At the distal end of the intermediate element is a probe head 5 with a stimulation electrode 5a that is electrically conducting and inherently connected to the conductor 1A in order to deliver stimulating pulses to a vein or other tissue (Col. 4, lines 38-52). As shown in figure 2, the retention structure comprises a plurality of annular reliefs, or screw threads 6, that possess an overall circular contour with a diameter greater than the diameter of the sheath 1b.

7. Regarding claims 2 and 6, figure 2 shows the circular contour to be eccentric relative to the first axis of the cylindrical body.

8. Regarding claims 7-9 and 11, figure 2 shows the plurality of annular reliefs to comprise a helicoid relief having a thread extending around the cylindrical body in a nonjointed way. Figure 2 further shows that the thread extends around the cylindrical body for approximately 3 turns, and that there is a constant distance between the thread turns.

9. Regarding claim 10, figure 1 shows the helicoid relief with first and second ends, with the thread having a variable radius that starts small at the distal, or first, end 3, rises as it extends back, and then decreases to a small radius again at the proximal, or second, end (Col. 6, lines 13-24).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

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be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka. Osypka, as described above, discloses the applicant's basic invention, including the circular contour of the threads being on a second axis. As shown in figure 2, the threads appear to be slanted back slightly, which would put it on a different axis than the cylindrical body. Osypka does not disclose,

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however, that the difference in the angle between the axes is between 15 and 25% of the diameter of the cylindrical body. However, upon reviewing the specification of the application, there does not appear to be any distinct reason or advantage for choosing the range of 15-25% of the diameter. Therefore, it would have been obvious matter of design choice to modify the axis of the threads by 15-25% since the applicant has not disclosed that having the threads off-axis in this range serves any particular purpose and it appears that the threads of Osypka would perform equally well, regardless of the amount that they are off-axis.

14. Regarding claim 4, Osypka, as described above, discloses the applicant's basic invention, including the overall circular contour having a diameter greater than the diameter of the cylindrical body. Osypka does not disclose, however, that the overall diameter is between 1.5 and 2 times the diameter of the cylindrical body. However, upon reviewing the specification of the application, there does not appear to be any distinct reason or advantage for choosing the range of 1.5-2 times the diameter. Therefore, it would have been obvious matter of design choice to modify the diameter of the overall circular contour by 1.5-2 times the diameter of the cylindrical body since the applicant has not disclosed that having the overall contour in this range serves any particular purpose and it appears that the threads of Osypka would perform equally well, regardless of their diameter when compared to the cylindrical body.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka in view of Audoglio (US 6,556,874, previously published 9/6/2001).

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Osyka, as described above, discloses the applicant's basic invention with the exception of the thread of the retention device having a round profile. Attention is directed to the secondary reference of Audoglio, which shows a helical retention element 16 with a round profile for affixing the lead to bodily tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the helicoid of Osypka by making them round as taught by Audoglio since this is a known profile for helical retention elements used in the body.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is

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571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766

EDB


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766